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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,145	08/22/2003	Bong Cheol Kim	DE-1501	8727
26111 7590 06/23/2009 STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005				
EXAMINER				
SOROUSH, LAYLA				
ART UNIT		PAPER NUMBER		
1617				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/646,145

Applicant(s)

KIM ET AL.

Examiner

LAYLA SOROUSH

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 146-244 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 146-244 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SE-US)
Paper No(s)/Mail Date 3/6/09
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on April 6, 2009 has been entered. Claims 146-244 are pending.

See rejections below:

Claim Rejections - 35 USC § 11 2

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any : person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 146, 149-176, 178-203, 204, and 207-232 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for inhibition of IgE production or inhibiting histamine release in a mammal in need thereof, said method comprising administering an extract of kiwifruit of the genus *Actinidia* to said mammal, a mammal in need thereof, said method comprising administering an extract of kiwifruit of the genus *Actinidia* to said mammal, the specification does not enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl's 1986) at 547 the court recited eight factors:

(1) the nature of the invention', (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims', (6) the amount of direction or guidance presented', (7) the presence or absence of working examples', and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1). The Nature of the Invention: All of the rejected claims are drawn to an invention which pertains to inhibition of IgE production or inhibiting histamine release in a mammal in need thereof, said method comprising administering an extract of kiwifruit of the genus *Actinidia* to said mammal, a mammal in need thereof, said method comprising administering an extract of kiwifruit of the genus *Actinidia* to said mammal.

(2). The state of the prior art: The prior art teaches with respect to asthma that there is still scope for greater use of preventive medications and management practices to reduce morbidity but it seems unlikely that further improvements in treatment methods will lead to significant reductions in prevalence (Peat, The Epidemiology of Asthma, page 11 last par).

(3). The predictability or unpredictability of the art: the state of the art for inhibition of IgE production or inhibiting histamine release is relatively low.

(4). The breadth of the claims: the claims encompass a method of inhibiting or reducing IgE production and histamine release in a mammal. Applicant fails to set forth the criteria that accurately define the inhibition of IgE production and histamine release in a mammal.

(5). The amount of direction or guidance presented: does not provide any guidance in term of inhibition of IgE production and histamine release in a mammal. Table 9 lists a 62.5% inhibition rate of edema in mice that were orally administered *Actinidia* kiwifruit extract. The Examiner states that the specification fails to enable one of ordinary skill in the art to practice the presently claimed method for inhibiting IgE production and histamine release in a mammal. The term "inhibit" or "inhibiting" is synonymous with the term "prevention" or "curing" and all circumscribe methods of treatment having absolute success. Since absolute success is not as of yet reasonably possible with most diseases/disorders, the specification is viewed as lacking

Art Unit: 1617

an adequate enablement of inhibiting IgE production and histamine release in a mammal.

(6). The presence or absence of working examples: Applicant does not provide any working examples for the inhibition of IgE production and histamine release in a mammal. The applicant has not provided any competent evidence or disclosed any tests that are highly predictive for the inhibition effects of the instant composition. The Examiner states Applicants' definition of 62.5% inhibition rate of edema is not in fact inhibition but is reduction.

(7). The quantity of experimentation necessary: the quantity of experimentation would be an undue burden to one of ordinary skill in the art and amount to the trial and error type of experimentation. Thus, factors such as "sufficient working examples, "the level of skill in the art' and "predictability" etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims. In view of the breadth of the claims, unpredictability of inhibition of IgE production and histamine release in a mammal, and the lack of working examples regarding the activity as claimed – to inhibit--, one skilled in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 146-153, 155-183, 185-211, 213-244 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murad (US 6,630,163), of record, in view of Endres et al. (DE 19758090 A1) and/or Udagawa (JP 61140510 A) and/or Luo et al. (CN1107308A), and Tsuboi et al. (JP 02202808 A), Wuthrich (Serum IgE in atopic dermatitis; Clinical & Experimental Allergy Volume 8 Issue 3, Pages 241 - 248), Lukacs et al. (US 20020006410 A1), and Capetola et al. (US4444780 A).

Murad teaches a method of treating dermatological disorders, including those of inflammatory nature such as inflammatory dermatoses, with fruit extracts, including kiwi fruit extract. See col. 8, lines 10-29. The fruit extract is present in an amount of 0.01-80 wt. %. See col. 8, lines 13-16. Murad teaches the same amounts of the extract. The dermatological agent may be administered orally or topically (col 6 line 30).

While broadly teaching "kiwi fruit", Murad does not explicitly teach the claimed species of kiwi fruit nor the extraction process.

However, Endres et al., Udagawa, and Luo et al. show that extracts of the claimed species of kiwi fruit are known in the art and used in cosmetics and

Art Unit: 1617

pharmaceuticals. See respective Abstracts. Udagawa teaches "The kiwi fruit solution also can be used as a starting material for food (see abstract)."

Additionally, Tsuboi et al. teaches an oral or topical composition of kiwi extract comprising administering two times amount of water is added to kiwi fruit after heat treatment. The fruit is crushed, filtered, and then ethanol is added to same amount of resultant crude solution. The solution is stirred, then aged by leaving at rest in cooling place for a whole day and night, preferably 2-3 days, and filtered by filter paper, with concentrating as necessary (abstract). The amount ethanol used ranges from 0-80%. Tsuboi et al. teaches the kiwi extract has excellent solubility in water system.

Wuthrich is solely used to show that atopic dermatitis is associated with an increase in IgE production.

Lukacs et al. is solely used to show that in treating inflammatory disease results in a decrease in the production of Th2-type antibody isotypes, such as IgG1 and IgE, and/or an increase in the production of Th1-type antibody isotypes, such as IgG2a or IgG3.

Capetola et al. is solely used to show the relationship between atopic dermatitis and histamine release and edema.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the claimed invention was made to use *Actinidia arguta*, *Actinidia kolomikta* or *Actinidia polygama* and the extraction method of Tsuboi et al. The motivation to use the *Actinidia arguta*, *Actinidia kolomikta* or *Actinidia polygama* of Endres et al., Udagawa, and Luo et al. and the extraction method of

Art Unit: 1617

Tsuboi et al. for compositions of Murad is because all are kiwi extracts useful in oral compositions and Tsuboi et al. teaches the kiwi extract has excellent solubility in water system. Therefore, the skilled artisan would reasonable expectation of achieving the desired therapeutic results. Selection of a known material based on its suitability for its intended use is obvious absent a clear showing of unexpected results attributable to the applicant's specific selection. See e.g., *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Claims 154, 184, and 212 as being unpatentable over Murad (US 6,630,163), of record, in view of Endres et al. (DE 19758090 A1) and/or Udagawa (JP 61140510 A) and/or Luo et al. (CN1107308A) and Tsuboi et al. (JP 02202808 A), Wuthrich (Serum IgE in atopic dermatitis; Clinical & Experimental Allergy Volume 8 Issue 3, Pages 241 - 248), Lukacs et al. (US 20020006410 A1), and Capetola et al. (US4444780 A) and further in view of Suzuki et al. (US 20020054923 A1).

Murad is as discussed above.

Murad fails to teach the non-polar solvent ethyl acetate.

Suzuki et al. teaches kiwi fruit can be extracted with water, ethanol, methanol, acetic acid, chloroform, dichloromethane, ethyl acetate, n-hexane, acetone, benzene, petroleum ether, ether or the like.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the claimed invention was made to use the non-polar solvent ethyl acetate. The motivation to use the solvent ethyl acetate of Suzuki

Art Unit: 1617

et al. for compositions of Murad is because Suzuki et al. teaches kiwi fruit can be extracted with water, ethanol, methanol, acetic acid, chloroform, dichloromethane, ethyl acetate, n-hexane, acetone, benzene, petroleum ether, ether or the like. Therefore, the skilled artisan would have a reasonable expectation of achieving the desired therapeutic results.

Claims 146-153, 155-183, 185-211, 213-244 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forastiere et al. ("Consumption of fresh fruit rich in vitamin C and wheezing symptoms in children", Thorax 2000, 55: 283-288), cited by the Applicant, in view of Endres et al. (DE 19758090 A1) and/or Udagawa (JP 61140510 A) and/or Luo et al. (CN1107308A) and further in view of Lee et al. (Oral Administration of IL-12 Suppresses Anaphylactic Reactions in a Murine Model of Peanut Hypersensitivity Clinical Immunology Vol. 101, No. 2, November, pp. 220-228, 2001) and Wei (US 5177060 A).

Forastiere et al. teach consumption of kiwi fruit reduced the occurrence of asthmatic symptoms, which might be attributed to an anti-inflammatory action of vitamin C. See pp. 283, 285. Further, kiwi fruit is known to contain sugars. Furthermore, the kiwi fruit juice extracted during eating the fruit is liquid and is soluble in water and alcohol. Forastiere et al. do not explicitly teach the concentration of the extract. However, it is believed that if the entire fruit is a "composition", the fruit juice extracted during eating the fruit would constitute roughly from one third to half of the entire fruit, depending on its ripeness, and, therefore, meet the concentration limitations of the instant claims.

While broadly teaching "kiwi fruit", Forastiere does not explicitly teach the claimed species of kiwi fruit nor an extraction process.

However, Endres et al., Udagawa, and Luo et al. show that extracts of the claimed species of kiwi fruit are known in the art and used in cosmetics and pharmaceuticals. See respective Abstracts. Udagawa teaches "The kiwi fruit solution also can be used as a starting material for food (see abstract)."

Additionally, Tsuboi et al. teaches an oral or topical composition of kiwi extract comprising administering two times amount of water is added to kiwi fruit after heat treatment. The fruit is crushed, filtered, and then ethanol is added to same amount of resultant crude solution. The solution is stirred, then aged by leaving at rest in cooling place for a whole day and night, preferably 2-3 days, and filtered by filter paper, with concentrating as necessary (abstract). The amount ethanol used ranges from 0-80%. Tsuboi et al. teaches the kiwi extract has excellent solubility in water system.

Lee et al. is solely used to show that allergic asthma is associated with histamine release, serum IgE, IgG1, IgG2, Th2, and Th1 levels.

Wei et al. is solely used to show the relationship between asthma and edema.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the claimed invention was made to use *Actinidia arguta*, *Actinidia kolomikta* or *Actinidia polygama* and the extraction method of Tsuboi et al. The motivation to use the *Actinidia arguta*, *Actinidia kolomikta* or *Actinidia polygama* of Endres et al., Udagawa, and Luo et al. and the extraction method of

Art Unit: 1617

Tsuboi et al. for compositions of Forastiere is because all are kiwi extracts useful in oral compositions and Tsuboi et al. teaches the kiwi extract has excellent solubility in water system. Therefore, the skilled artisan would reasonable expectation of achieving the desired therapeutic results. Selection of a known material based on its suitability for its intended use is obvious absent a clear showing of unexpected results attributable to the applicant's specific selection. See e.g., *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Claims 154, 184, and 212 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forastiere et al. ("Consumption of fresh fruit rich in vitamin C and wheezing symptoms in children", *Thorax* 2000, 55: 283-288), cited by the Applicant, in view of Endres et al. (DE 19758090 A1) and/or Udagawa (JP 61140510 A) and/or Luo et al. (CN1107308A) and further in view of Lee et al. (Oral Administration of IL-12 Suppresses Anaphylactic Reactions in a Murine Model of Peanut Hypersensitivity *Clinical Immunology* Vol. 101, No. 2, November, pp. 220-228, 2001) and Wei (US 5177060 A) and further in view of Suzuki et al. (US 20020054923 A1).

Forastiere is as discussed above.

Forastiere fails to teach the non-polar solvent ethyl acetate.

Suzuki et al. teaches kiwi fruit can be extracted with water, ethanol, methanol, acetic acid, chloroform, dichloromethane, ethyl acetate, n-hexane, acetone, benzene, petroleum ether, ether or the like.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the claimed invention was made to use the non-polar

Art Unit: 1617

solvent ethyl acetate. The motivation to use the solvent ethyl acetate of Suzuki et al. for compositions of Forastiere is because Suzuki et al. teaches kiwi fruit can be extracted with water, ethanol, methanol, acetic acid, chloroform, dichloromethane, ethyl acetate, n-hexane, acetone, benzene, petroleum ether, ether or the like. Therefore, the skilled artisan would have a reasonable expectation of achieving the desired therapeutic results.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed April 6, 2009 have been fully considered. The response to the arguments is as discussed below:

Applicant argues that Murad compositions are not used in treatment of allergic diseases or non-allergic non-dermatological inflammatory diseases. Examiner's contention is that Murad in fact teaches a method of treating dermatological disorders, including those of inflammatory nature such as inflammatory dermatoses, with fruit extracts, including kiwi fruit extract. See col. 8, lines 10-29. Inflammatory dermatoses encompasses the limitation atopic dermatitis.

Applicant argues the Examiner erred in determining the content of Endres reference. More specifically, the Applicant states the Endres reference fails to teach allergic diseases. The Examiner states that Endres teaches the hardy kiwi

Art Unit: 1617

juice is used in treating psoriasis an allergic inflammatory disease (also see Pegg et al. US 5955463 A col 11 lines 20-25).

The argument that Udagawa is not useful for oral administration is not persuasive. Udagawa teaches "The kiwi fruit solution also can be used as a starting material for food (see abstract)."

With respect to the argument regarding Lukacs et al. and the production of Th2-type antibody isotypes, such as IgG1 and IgE, and/or an increase in the production of Th1-type antibody isotypes, such as IgG2a or IgG3, the Examiner states: The inflammatory diseases taught by Lukacs et al. include allergic airway diseases, hyper-eosinophilic syndrome, helminthic parasitic infection, allergic rhinitis, allergic conjunctivitis, dermatitis, eczema, contact dermatitis, or food allergy. Hence, a skilled artisan would know from the teaching of Lukacs that the diseases claimed would in fact modify the production of Th2-type antibody isotypes, such as IgG1 and IgE, and/or an increase in the production of Th1-type antibody isotypes, such as IgG2a or IgG3.

Applicant argues the Forastiere reference fails to teach the treatment of symptoms anaphylaxis, allergic rhinitis, allergic conjunctivitis, allergic dermatitis, atopic dermatitis, contagious dermatitis, urticaria, insect allergy, food allergy and drug allergy. The Examiner states that asthma can be a symptom of i.e. food allergies.

Additionally, with respect to the argument that the specific extract *Actinidia* is not taught by Murad, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce

Art Unit: 1617

the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the claimed invention was made to use *Actinidia arguta*, *Actinidia kolomikta* or *Actinidia polygama* of Endres et al. or Udagawa for method of Forastiere et al. with a reasonable expectation of achieving the desired therapeutic results.

Lastly, upon consideration of claimed benefit US Provisional application 60/405,295 the Examiner finds that there is no support for certain allergic diseases (i.e., allergic conjunctivitis, contagious dermatitis, insect allergy), dilution ratios, concentration ranges, and solvents claimed herein. Therefore, the priority of 08/23/2002 is not granted.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or

Art Unit: 1617

proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617